



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2012
EMA/CHMP/119670/2012 Corr*
Press Office

Press release

European Medicines Agency gives final recommendations for 12 centrally authorised medicines manufactured at Ben Venue Laboratories

Final recommendations confirm interim advice given
Medicines can continue to be prescribed as previously

Continuing its review on the shortcomings in quality assurance identified at Ben Venue Laboratories, Ohio, USA, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has confirmed its initial advice and given final recommendations for 12 out of 14 centrally authorised medicines manufactured at this site (Angiox, Busilvex, Vidaza, Vistide, Velcade, Ecalta diluent, Soliris, Cayston, Luminity, Mepact, Torisel and Vibativ). These medicines can continue to be prescribed as previously.

On 13 January 2012, the UK's medicines regulatory agency (MHRA) on behalf of the European regulatory network issued a restricted Good Manufacturing Practice Certificate to Ben Venue in order to stop the EU supply of non-essential medicines from Ben Venue, while allowing the continued supply of essential medicines.

The CHMP has now asked the marketing authorisation holders for the 12 centrally authorised medicines to remove Ben Venue Laboratories, Ohio as manufacturing site from the marketing authorisation.

For Vibativ and Luminity, which are currently not marketed in the EU and for which no alternative manufacturer or formulation is available, the Committee recommends the suspension of the marketing authorisations until a suitable alternative manufacturing site is approved. For the remaining 10 medicines, the CHMP recommends maintaining the marketing authorisations as alternative suppliers or formulations are available.

* Previously it was stated incorrectly that for Vistide and Cayston, Ben Venue Laboratories, Ohio had already been removed as the manufacturing site from the marketing authorisation.



The review of the two other centrally authorised medicines manufactured at this site, Caelyx and Ceplene, is still ongoing and is expected to be concluded in March 2012.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The European review of the centrally authorised medicines Angiox, Busilvex, Cayston, Ecalta, Luminity, Mepact, Soliris, Torisel, Velcade, Vibativ, Vidaza and Vistide, manufactured at the Ben Venue site in Ohio, was conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, on 17 November 2011. More information on these medicines can be found in the relevant European public assessment reports (EPARs).
3. The press releases on the interim recommendations for medicines manufactured at Ben Venue dated 22 November 2011, 9 and 13 December 2011 are available on the Agency's website.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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